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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,625	02/07/2000	WINOK DEBYSER	BJS-550-392	7510
23117 7590 11/15/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER FRONDA, CHRISTIAN L	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 11/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/403,625

Applicant(s)

DEBYSER ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2007 has been entered.
2. Claims 51 and 57 are pending and under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 51 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is based upon the written description rejection set forth in a prior Office Action, mailed on 11/18/2004 and the Examiner's Answer mailed on 06/29/2005.
The claims are genus claims that encompass to a genus of any xylanase inhibitors which are water-soluble, alkaline proteins or glycoproteins that have a molecular weight of 40-43 kDa, pI of greater than about 7.0, have the N-terminal amino acid sequence which is 70% homologous to SEQ ID NO: 1, where SEQ ID NO: 1 is a sequence of 14 amino acids, said inhibitors resolving as two separate bands on SDS-PAGE after reduction with β -mercaptoethanol having an amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2, respectively. It is known in the art that the average molecular mass of an amino acid residue in a protein is about 0.11 kDa (See Proteins : Structures and Molecular Properties, 2nd ed.(1993), Thomas E. Creighton, p. 4, Table

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1.1; reference made of record). Thus, the claimed genus encompasses proteins or glycoproteins that have amino acid sequences that contain approximately 333-358 amino acid residues since the claims recite a molecular weight of about 40-43 kDa. It should be noted that SEQ ID NO: 1 is a minimal amino acid sequence that accounts for only 14 out of approximately 333-358 amino acids residues contained within the claimed genus of proteins and glycoproteins since SEQ ID NO: 1 is only 14 amino acids in length.

The scope of the claim includes many proteins and glycoproteins with widely differing structural, chemical, biological, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists.

The specification discloses a xylanase inhibitor which is a water-soluble, alkaline protein obtained from wheat having a molecular weight of 40-43 kDa, pI of greater than about 7.0, and consisting of two subunits with a partial N-terminal amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2 (see specification p. 20, lines 1-16). The specification does not provide any sequence information for the disclosed rye and barley xylanase inhibitors. For the wheat xylanase inhibitor, the specification only provides minimal amino acid sequence information that identifies 31 amino acid residues out of approximately 333-358 amino acid residues of the wheat xylanase inhibitor, as evident by the 14 amino acids in SEQ ID NO: 1 and 17 amino acids in SEQ ID NO: 2. Since only 31 amino acids have been identified, then only 8.7%-9.3% of the entire amino acid sequence of the wheat xylanase inhibitor has been disclosed by the specification.

The specification, however, does not describe any significant amino acid sequence and structure which is common to all members of the claimed genus. The specification does not disclose that the rye and barely xylanase inhibitors have both the minimal structures of SEQ ID NO:1 and SEQ ID NO: 2 of the wheat xylanase inhibitor. The specification does not describe a well-established correlation between the disclosed minimal structures of SEQ ID NO:1 and SEQ ID NO: 2 to any function. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

Since the specification fails to describe a well-established correlation between the disclosed minimal structure of SEQ ID NO: 1 and SEQ ID NO: 2 to any function, and the specification fails to describe that the rye and barely xylanase inhibitors have the minimal structure of SEQ ID NO:1 and SEQ ID NO: 2, then one skilled in the art cannot predict, visualize, and recognize the identity of other members of the claimed genus of xylanase inhibitors. Thus, applicant was not in possession of the claimed genus.

Conclusion

5. No claim is allowed.


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6. This is a continuation of applicants' earlier Application No. 09/403,625. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday- Friday from 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N. Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000. CLF


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